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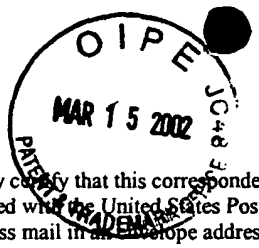

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

By _____
Amelia Groth

Attorney Docket No. 1012-010100US
Client Ref. No. SJK/FP5872916

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
RADEMACHER, Thomas William, et al.

Application No.: 09/622,253

Filed: February 5, 1999

For: DERIVATISED ANTIBODIES WITH EXPOSED CARBOHYDRATE CHAINS CAPABLE OF BINDING TO IMMOBILISED IGG

Examiner: Gerald R. Ewoldt

Art Unit: 1644

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please reconsider the Restriction Requirement mailed December 7, 2001, in light of the remarks below.

The following documents are submitted herewith:

1) A transmittal sheet;
2) A fee transmittal sheet;
3) A petition for extension of time through the present date; and,
4) A receipt indication postcard.

RESPONSE TO RESTRICTION REQUIREMENT

Applicants elect proposed Group I, with traverse.

TRAVERSAL OF RESTRICTION REQUIREMENT

Applicants traverse the restriction requirement, as noted in more detail below.

The Invention Does Not Lack Unity of Invention

The Examiner alleges that Applicants' invention lacks unity of invention and imposes a restriction requirement. The Examiner alleges that Applicants' invention lacks unity of invention because unity of invention does not include multiple methods of producing products. Applicants traverse.

According to the MPEP 1893.03(d) Unity of Invention, "an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept." "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression 'special technical features' is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art." *Id.* Applicants' invention relates to derivatised antibodies that possess the characteristic of binding to an immobilised IgG. This common special technical feature is found throughout all the claims of the Applicants' application. The Examiner has failed to cite any prior art that relates to this unifying feature.

In addition, as stated in 37 CFR 1.475, MPEP § 1850 and in the Action (page 2, no. 3), unity of invention can exist with combinations of different categories of claims if specific combinations of inventions are present, which include the following: 1) a product and a special process of manufacture of said product; 2) a product and a process of use of said product; 3) a product, a special process of manufacture of said product, and a process of use of said product; 4) a process and an apparatus specially designed to carry out said process; and 5) a product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process. Furthermore, "[a] process is 'specially adapted' for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and the claimed product. The expression 'specially

adapted' does not imply that the product could not also be manufactured by a different process." MPEP § 1893.03(d).

Although the Examiner alleges that none of these specific combinations exits, this is simply incorrect. Applicants' application is drawn to methods, products and process using the products of derivatised antibodies that possess the characteristic of binding to an immobilised IgG as described above as specific combination number 3 and described as specific combination C in the restriction requirement. Specifically, claims 1 to 6 are directed to a method of derivatising an antibody (a special process for the manufacture of a product); claims 7 to 21 and 23 are directed to the derivatised antibody made by the method of claim 1 (product) and use of the derivatised antibody (process of use of the product); and claim 22 is directed to the diagnostic use of these derivatised antibodies (process of use of the product). As described above, the derivatised antibody that is capable of binding to an immobilised IgG provides the technical relationship between the product (a derivatised antibody), the special process of manufacture of the derivatised antibody and the process of use of the derivatised antibody. Since there is at least one common or corresponding technical feature in the different proposed categories of claims (process, product and process of use) and the Examiner has failed to cite any art to the contrary, Applicants' invention has unity of invention and the restriction requirement should be withdrawn.

<u>If at all, Linking Claim Restriction Practice Should Be Applied</u>

Applicants submit that even if the Examiner improperly maintains the lack of unity of invention, the Examiner still must apply linking claim restriction practice in this case. The restriction requirement would then be properly conditioned on the nonallowance of any linking claims. *See* MPEP § 809.04. According to the MPEP §809.03, "[t]here are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the application to one would be proper, but presented in the same case are one or more claims (generally called 'linking' claims) inseparable therefrom and thus linking together the inventions otherwise divisible. The most common types of linking claims which, if allowed, act to prevent restriction between the inventions that can otherwise be shown to be divisible, are (A) genus claims linking species claims; (B) a claim to the necessary process of making a product linking proper process and product claims; (C) a claim to "means"

for practicing a process linking product apparatus and process claims; and, (D) a claim to the product linking a process of making and a use (process of using)."

Claim 1 (and its dependent method claims 2-6) is drawn to a method of producing a derivatised antibody. Claim 7 (and its dependent claims 8-17) is drawn to a derivatised antibody made by the method of claim 1, while dependent claims 18-21 are drawn to a medicament comprising the derivatised antibody of claim 7 made by the method of claim 1. Claim 22 is drawn to a method for the in vivo diagnosis of a condition associated with immobilised IgG using the derivatised antibody of claim 7 which is made by the method of claim 1. Finally, claim 23 is drawn to a pharmaceutical composition comprising a derivatised antibody made by the method of claim 1. Claim 1 is a linking claim to claims 7-23. Claim 1 is "a claim to the necessary process of making a product linking proper process and product claims" as described above in MPEP § 809.03 (B). Thus, even if the Examiner improperly maintains the rejection for lack of unity, the dictates of the MPEP at § 809.03(B) must be followed.

Furthermore, if the Examiner maintains the improper restriction of claims 1-6 into Groups I, II and III, linking restriction practice also applies in this situation. Dependent claim 5 adds the limitation of "separating derivatised antibodies which can associate with one another at a site of the immobilised IgG, from those derivatised antibodies which cannot so associate." Claim 6 further defines the separation limitation of claim 5 to be where "separating the derivatised antibody is performed by Con A chromatography or by pH elution from a Protein A affinity column." Claim 5 is a genus claim linking the species described in claim 6. In addition, according to MPEP § 809.02 "[u]nder 37 CFR 1.141, an allowed generic claim may link a reasonable number of species embraced thereby." Claim 6 is drawn to a reasonable number of species, two, linked to generic claim 5. Thus, according to MPEP § 809.03 (A), if the Examiner is going to apply a restriction requirement to claims 1-6, the Examiner should apply linking claim restriction practice to these claims.

A linking claim restriction is contingent on the allowance of the linking claim. The Examiner has presented no evidence that the linking claims are not allowable. As a result, the restriction requirement must be withdrawn.

<u>The Restriction Requirement Does Not Conform to PTO Restriction Practice</u>

Applicants also submit that the Examiner's restriction requirement does not conform to PTO restriction practice. As enumerated in the Restriction Requirement, each of groups I-III comprises the same claims (1-5). Similarly, groups II and III each comprise the same claims (1-6). On its face, the restriction requirement is improper.

Applicants submit that the restriction of independent claim 1 and dependent claims 2-6 into separate groups (Groups I, II and III) impairs the scope of the claims as originally written and prevents Applicants from ever pursuing the original form of the claims. Restriction of independent claim 1 and dependent claims 2-5 into 3 separate groups (Groups I, II and III) and claim 6 into 2 of these separate groups (Groups II and III), presumably based upon the separation step that is used separate the derivatised antibody, and the like, does not provide for the sum of the parts to equal the whole, which is the current PTO policy regarding restriction. Specifically, claim 1 is drawn to methods for "producing a derivatised antibody, which derivatised antibody is capable of binding to an immobilised IgG, the method comprising: treating a precursor antibody to expose a carbohydrate chain of the precursor antibody from an interstitial site on the surface of the precursor antibody; and, chemically derivatising the precursor to prevent the carbohydrate chain from returning to the interstitial site so that the resulting derivatised antibody is capable of binding to the immobilised IgG." As described above, dependent claim 5 adds a separation limitation and Claim 6 defines two types of species of the generic claim 5. Since the restrictions were not a species election for the purpose of examination, Applicants submit that the restrictions were completely improper, and should, therefore, be withdrawn.

Instead of improperly imposing a restriction requirement, the Examiner may limit initial examination to a reasonable number of species encompassed by the claim. See 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the Patent Office regarding administrative considerations and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See MPEP* at 803.02. *See also, In Re Wolfrum*, 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 USPQ 250 (C.C.P.A 1973). Unlike the restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to

file multiple divisional applications, which are simply incapable of capturing the intended scope of the invention.

Applicants submit that groups I (claims 1-5); II (claims 1-6); III (claims 1-6); IV (claims 7-21 and 23); and V (claim 22) have been improperly restricted because they do not lack unity of invention. Even assuming, arguendo, that Applicants' application lacked unity of unity of invention, which is does not, groups I, II, III, IV and V have been improperly restricted because the Examiner did not applied linking claim restriction practice and/or election of species. If linking claim restriction practice is applied, claim 1 (Group I, II and III), with dependent claims 2-6, is a linking claim to claims 7-21 and 23 (Group IV) and claim 22 (Group V) and claim 5 is a linking claim to claim 6.

Applicants also submit that groups I (claims 1-5); II (claims 1-6), and III (claims 1-6), as stated in the Office Action have been improperly restricted. Applicants respectfully submit that the restriction of claims 1, 2, 3, 4, 5 and 6 into multiple groups is improper, and that the Office is simply forbidden from restricting a single claim (i.e., 1, 2, 3, 4, 5,and 6) into multiple groups, because 1) such a restriction is necessarily a rejection of the claim (i.e., there is no application where an applicant is permitted to pursue the claim as drafted); and 2) the court has explicitly held that § 121 does not provide a basis for such a rejection (and the court has, quite bluntly, held that this is a per se holding). *See In Re Weber, Soder and Boksay*, 198 USPQ 328, 331-332, 338 (C.C.P.A. 1978); *In Re Haas I*, 179 USPQ 623, 624, 625 (C.C.P.A. 1978); and, *In Re Haas II*, 198 USPQ 334, 335 (C.C. P.A. 1978).

Because the restriction is improper, Applicants respectfully request that the groups be rejoined. Applicants also request that if the Examiner maintains the restriction requirement, the restriction requirement should be properly conditioned on the nonallowance of the linking claims.

Finally, Applicants note that the courts have explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. *See In Re Haas I, supra*. Because restriction of a single claim into multiple groups is a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have

jurisdiction over the decision. Accordingly, Applicants expressly reserve the right to appeal any decision that may be made regarding the present Restriction Requirement to the Patent Office Board of Appeals and to the Federal Circuit, in this or any future related application.

CONCLUSION

The Restriction Requirement Should be Withdrawn.

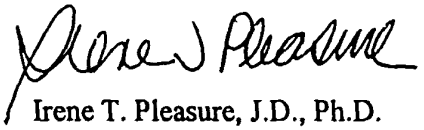
As set forth above, the restriction requirement in the present case should be withdrawn. There is no lack of unity of invention. This is supported by the arguments expressed above. Furthermore, a 5-way restriction in the present case clearly violates the firm dictates of the Patent Office practice regarding restriction practice as set forth in the MPEP. Even if there was a lack of unity of invention, which there is not, at most this should have been an election of species or restriction requirement conditioned on the nonallowance of linking claims.

To conform to the requirements of the restriction order, Applicants have elected, with traverse, that claims 1-5 (Examiner's Group I) be examined in the present invention. However, Applicants traverse the restriction requirement in the strongest terms.

In the event that requirement is maintained, Applicants hereby request an interview with the Examiner, Supervisory Examiner Christina Chan and group Director John Doll before issuance of any additional action by the Examiner.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-337-7971.

Respectfully submitted,



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